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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/807,079 | 04/06/2001 | Ralph Weisheit | BMID9818US | 2314 |

7590 06/13/2003
BRINKS HOFER GILSON & LIONE
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EXAMINER

GITOMER, RALPH J

| | |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1651

DATE MAILED: 06/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/807,079

Applicant(s)
Weisheit et al.

Examiner
Ralph Gitomer

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 2, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-32 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

The amendment received 5/5/2003 and the Change of Address received 6/2/2003 have been entered and claims 12-32 are currently pending in this application. Priority is granted to 08
5 October 1998, please update the specification accordingly.

In view of the arguments presented and amendments to the claims, all the rejections of record are hereby withdrawn. This Office Action is made non-final because new rejections follow.

10 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

15 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be
20 negated by the manner in which the invention was made.

25 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103[©] and

potential 35 U.S.C. 102(f) or (g) prior art under 35
U.S.C. 103(a).

Claims 12-32 are rejected under 35 U.S.C. 103(a) as being
unpatentable over the combination of Siedel in view of Weisheit.

Siedel (6,013,467) entitled ~~✖~~Blood Substitute Suppression by
Peroxides~~✖~~ published 1/1998, teaches in column 1, determining
alkaline phosphatase where hemoglobin is present in the sample,
usually >500 mg/dl. Higher levels can occur. In column 2
measurements are made at 380-450 nm and 520-590 nm where
hemoglobin has its main and secondary absorptions. Modified
hemoglobins are shown including diaspirin cross-linked
hemoglobin. See claim 5 in column 10.

The claims differ from Siedel in that they additionally
recite secondary wavelengths of 480, 546 and 575 nm.

Weisheit (WO 97/45733) entitled ~~✖~~Process to Eliminate
Hemoglobin Errors When Analyzing Medical Samples,~~✖~~ English
translation, teaches on page 2, a process for determining an
analyte containing hemoglobin by optical bichromatic measurement
with a main and a secondary wavelength. On page 4 different
forms of hemoglobin are described. On page 4 last paragraph
bridging to page 5, secondary wavelengths of 546 and 570 plus or
minus 10 nm are shown. See claim 4 on page 18.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the secondary measurements as taught by Weisheit in the method of Siedel because the secondary wavelengths taught by Weisheit are employed for the same function as those taught by Siedel. And the present claims also include the secondary wavelengths of Siedel. Regarding the dependent claims, the references teach both plasma and serum samples, as well as the presently claimed forms of hemoglobin. Regarding claims 22 and 23 directed to concentrations of hemoglobin, the references teach high concentrations of hemoglobin which would encompass those claimed. No criticality to the claimed wavelengths is seen and no specific function for them is claimed.

Claims 12-32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

Claims 12, 24 and 28 are incomplete in that there are no method steps presented to accomplish the preamble.

Serial No. 09/807,079
Art Unit 1651

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button Patent Electronic Business Center for more information.

Ralph Gitomer

Ralph Gitomer
Primary Examiner
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